

Attorney's Docket No: L0461/7118 (JRV)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Martelange et al.
Serial No: Unknown
Filed: Herewith
For: TUMOR ASSOCIATED NUCLEIC ACIDS AND USES THEREFOR

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination, please amend the application as follows:

In the Claims:

Please cancel claims 1-24 and 29-43. Please substitute the following claims for the currently pending claims. Applicants have included herewith pages showing the markups of the claims with insertions and deletions indicated by underlining and bracketing, respectively.

25. A method for diagnosing a disorder characterized by expression of a tumor associated nucleic acid molecule, comprising:

contacting a biological sample isolated from a subject with an agent that selectively binds the tumor associated nucleic acid molecule, wherein the tumor associated nucleic acid molecule hybridizes under stringent conditions to a molecule having a nucleotide sequence set forth as SEQ ID NO:42 or its complement, wherein the stringent conditions are hybridization at 65°C in hybridization buffer (3.5 x SSC, 0.02% Ficoll, 0.02% polyvinyl pyrrolidone, 0.02% Bovine Serum Albumin, 25mM NaH₂PO₄ (pH 7), 0.5% SDS, 2mM EDTA) and wherein SSC is 0.15M sodium chloride/0.015M sodium citrate, pH 7; SDS is sodium dodecyl sulphate; and EDTA is ethylenediaminetetracetic acid, and

determining expression of the tumor associated nucleic acid molecule in the sample, wherein the expression of the tumor associated nucleic acid molecule is diagnostic for the disorder in the subject.

26. The method of claim 25 wherein the agent is a nucleic acid molecule comprising a molecule comprising a nucleotide sequence set forth as SEQ ID NO:42, fragments thereof, and complements thereof.

27. The method of claim 25, wherein the agent comprises a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:42 or a fragment thereof.

Please add the following new claims.

44. The method of claim 25, wherein the expression of the nucleic acid molecule in the sample is determined by determining the binding between the agent and the nucleic acid molecule.

45. The method of claim 44, wherein the binding between the agent and the nucleic acid molecule is determined by nucleic acid amplification.

46. The method of claim 45, wherein the nucleic acid amplification is reverse transcribed polymerase chain reaction (RT-PCR).

47. The method of claim 45 wherein the binding is determined by amplifying at least a portion of the tumor associated nucleic acid molecule.

48. The method of claim 44, wherein the binding between the agent and the nucleic acid molecule is determined by a Northern blot assay.

49. The method of claim 25, wherein the disorder is cancer.

50. The method of claim 49, wherein the cancer is selected from the group consisting of lung carcinoma, non-small cell lung cancer, epidermoid carcinoma, sarcoma and head & neck carcinoma.

Remarks

Applicants respectfully request that the Examiner base examination upon the amended claims. Applicants have canceled claims 1-24 and 29-43, leaving original claims 25-28 which correspond to group III of the restriction requirement imposed in the parent application (serial number 09/567,995). Original claim 29, in amended form, is now claim 47. Support for the amendments is found in the claims as filed.

Applicants have added claims 44-50 which claim subject matter within this restriction group (diagnostic methods using nucleic acids). Claims 44-50 are supported in the specification and claims as filed, particularly in the Examples. No new matter has been added.

In view of the foregoing amendments, favorable action is respectfully requested. The Examiner is invited to contact the undersigned to advance the prosecution in any respect.

Respectfully submitted,



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XNDD

Amended Claims

25. A method for diagnosing a disorder characterized by expression of a tumor associated nucleic acid molecule, comprising:

contacting a biological sample isolated from a subject with an agent that [is specific for] selectively binds the tumor associated nucleic acid molecule, wherein the tumor associated nucleic acid molecule hybridizes under stringent conditions to a molecule having a nucleotide sequence set forth as SEQ ID NO:42 or its complement, wherein the stringent conditions are hybridization at 65°C in hybridization buffer (3.5 x SSC, 0.02% Ficoll, 0.02% polyvinyl pyrrolidone, 0.02% Bovine Serum Albumin, 25mM NaH₂PO₄ (pH 7), 0.5% SDS, 2mM EDTA) and wherein SSC is 0.15M sodium chloride/0.015M sodium citrate, pH 7; SDS is sodium dodecyl sulphate; and EDTA is ethylenediaminetetracetic acid, and

determining [the interaction between the agent and] expression of the tumor associated nucleic acid molecule in the sample, wherein the expression of the tumor associated nucleic acid molecule is diagnostic for [as a determination of] the disorder in the subject.

26. The method of claim 25 wherein the agent is a nucleic acid molecule comprising a molecule [having] comprising a nucleotide sequence set forth as SEQ ID NO:42, fragments thereof, and complements thereof.

27. The method of claim 25, wherein the agent comprises a nucleic acid molecule [having] comprising the nucleotide sequence of SEQ ID NO:42 or a fragment thereof.

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Examiner: Unknown
Art Unit: Unknown

Box Patent Application
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Washington, D.C. 20231

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

[X] This Information Disclosure Statement has been filed within three months of the filing date of a National Application.

No fee or certification is required.

PART II - Information Cited

A. [X] The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

B. [] The Applicant hereby makes the following additional information of record in the above-identified application:

PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

The following are remarks concerning the other information cited:

PART IV: Remarks

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

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Docket No. L0461/7118

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